

In the Claims:

1. (currently amended) A film-shaped therapeutic system comprising at least two layers connected with each other for transmucosal administration of active substances, said at least two layers ~~includes~~ include a mucoadhesive layer which is mucoadhesive in an aqueous environment and a backing layer comprising at least one ~~polyacrylate~~ neutralized polymethyl methacrylate ~~[[layer]]~~ and serving as an active substance reservoir, wherein said backing layer is a boundary layer for reducing the permeation of water and the diffusion of active substances, relative to the other layer(s) of said system, ~~and at least one layer of said at least two layers of said system contains an active substance,~~ and wherein said mucoadhesive layer swells in an aqueous ~~[[media]]~~ medium but is insoluble or poorly soluble in the aqueous ~~[[media]]~~ medium and contains a polymer mixture, the polymer mixture comprising at least one hydrophile, mucoadhesive polymer embedded or dispersed in a polymer matrix, the polymer matrix comprising at least one polyvinyl alcohol, said mucoadhesive polymer being selected from the group consisting of polyacrylates and salts of polyacrylates, and said mucoadhesive layer further contains at least one active substance.
2. (currently amended) The film-shaped therapeutic system according to claim 1, wherein said mucoadhesive layer ~~substantially comprises~~ mainly consists of said polymer mixture, said polymer mixture being film-forming, capable of swelling in an aqueous ~~[[media]]~~ medium but ~~[[is]]~~ being insoluble or poorly soluble in the aqueous ~~[[media]]~~ medium.
3. (currently amended) The film-shaped therapeutic system according to claim 1, wherein said polymer mixture further comprises at least one hydrophile, mucoadhesive polymer

[[is]] selected from the group consisting of carboxyl groups-carrying hydrophilic adhesive polymers, ~~polyacrylates, salts of polyacrylates,~~ carboxymethyl cellulose, salts of carboxymethyl cellulose, poly(methyl vinyl ether maleic anhydride), aqueous hydrolysates of poly(methyl vinyl ether maleic anhydride), alcoholic hydrolysates of poly(methyl vinyl ether maleic anhydride) and salts of poly(methyl vinyl ether maleic anhydride).

4. (previously presented) The film-shaped therapeutic system according to claim 1, wherein said polymer matrix of said mucoadhesive layer is crosslinked by physical or chemical methods.

5. (canceled)

6. (currently amended) The film-shaped therapeutic system according to claim 1, wherein said backing layer contains at least one plasticizer ~~auxiliary substance selected from the group consisting of plasticizers, penetration enhancers, solubilizers, dyes, pigments and matrix formers.~~

7. (currently amended) The film-shaped therapeutic system according to claim 1, wherein adjacent layers of said system contain at least one identical or chemically ~~allied~~ related base polymer.

8. (previously presented) The film-shaped therapeutic system according to claim 1, wherein said system includes 2 to 6 layers.

9. (canceled)

10. (withdrawn) The film-shaped therapeutic system according to claim 1, wherein said system comprises at least three layers, wherein said at least three layers comprises a mucoadhesive layer, at least one middle reservoir layer and an outer backing layer, said

outer backing layer is a boundary layer for reducing the permeation of water and the diffusion of active substance, relative to the other layer(s) of said system.

11. (withdrawn) The film-shaped therapeutic system according to claim 10, wherein said boundary layer contains additives for reducing or blocking the diffusion of the active substance.

12. (withdrawn) The film-shaped therapeutic system according to claim 10, wherein said at least one reservoir layer contains at least one additive for increasing the swelling capacity and the hydration of the reservoir matrix, said at least one additive being a hydrophile, water-binding substance.

13. (previously presented) The film-shaped therapeutic system according to claim 1, wherein said at least one active substance is present in a form selected from the group consisting of dissolved, suspended and emulsified.

14. (previously presented) The film-shaped therapeutic system according to claim 1, wherein at least two layers contain the same active substance at different concentrations under formation of a concentration gradient.

15. (previously presented) The film-shaped therapeutic system according to claim 14, wherein the individual layers contain additives for modifying the solubility and diffusion coefficient of the active substance in the respective layer.

16. (withdrawn) A process for medicinal therapy or prophylaxis comprising the step of applying an active substance-containing film-shaped therapeutic system according to claim 1 onto the oral mucosa of a patient for a period of up to 24 hours for releasing at least one active substance with an initial burst dose and a subsequent maintenance dose.

17. (withdrawn) The process according to claim 16, wherein the release of said at least one active substance with an initial burst dose and a subsequent maintenance dose takes place for a period of 0.5 hour to 24 hours.
18. (currently amended) The film-shaped therapeutic system according to claim 7, wherein said at least one identical or chemically ~~allied~~ related base polymer is a polyacrylate.
19. (previously presented) The film-shaped therapeutic system according to claim 8, wherein said system includes 2 to 4 layers.
20. (withdrawn) The film-shaped therapeutic system according to claim 11, wherein said additives for reducing or blocking the diffusion of the active substance is an additive selected from the group consisting of pigments and diffusion-retarding polymers.
21. (withdrawn) The film-shaped therapeutic system according to claim 12, wherein said hydrophile, water-binding substance is selected from the group consisting of polyalcohols and polymeric surfactants with an HLB value of ≥ 10 .
22. (withdrawn) A process for medicinal therapy or prophylaxis according to claim 16, wherein the step of applying an active substance-containing film-shaped therapeutic system according to claim 1 onto the oral mucosa of a patient is for a period of up to 6 hours.
23. (new) The film-shaped therapeutic system according to claim 1, wherein said backing layer contains at least one penetration enhancer.
24. (new) The film-shaped therapeutic system according to claim 1, wherein said backing layer contains at least one solubilizer.

25. (new) The film-shaped therapeutic system according to claim 1, wherein said backing layer contains at least one auxiliary substance selected from the group consisting of dyes and pigments.

26. (new) The film-shaped therapeutic system according to claim 1, wherein said backing layer contains at least one matrix former.

27. (new) A film-shaped therapeutic system comprising at least two layer connected with each other for transmucosal administration of active substances, wherein said at least two layers include a mucoadhesive layer which is mucoadhesive in an aqueous environment and a backing layer comprising at least one polyacrylate and serving as an active substance reservoir, wherein said backing layer is a boundary layer for reducing the permeation of water and the diffusion of active substances, relative to the other layer(s) of said system, and at least one of said at least two layers of said system contains an active substance, and wherein said mucoadhesive layer swells in an aqueous medium but is insoluble or poorly soluble in the aqueous medium and contains a polymer mixture, the polymer mixture comprising at least one hydrophile, mucoadhesive polymer embedded or dispersed in a matrix, the matrix comprising at least one polyvinyl alcohol, said mucoadhesive polymer being selected from the group consisting of polyacrylates and salts of polyacrylates.